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10/521,380	01/06/2006	Thomas James McArthur	90885U	2136

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EXAMINER	
LEITH, PATRICIA A	

ART UNIT	PAPER NUMBER
1655	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/521,380	MCARTHUR, THOMAS JAMES	
	Examiner	Art Unit	
	Patricia Leith	1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *4/16/2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-7,12-14,20,22-42 and 47-67* is/are pending in the application.

4a) Of the above claim(s) *33-42 and 47-62* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-7,12-14,20,22-32 and 63-67* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *4/16/2010*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-7, 12, 14, 20, 23-25, 27, 30, 32, 63-65 and 67-70 are pending in this application.

Election/Restrictions

Claims 33-42 and 47-62 remain withdrawn from consideration on the merits as being directed toward a non-elected invention. These claims were cancelled in the most recent amendment submitted by Applicant on 4/9/2009.

Claims 1-7, 12, 14, 20, 23-25, 27, 30, 32, 63-65 and 67-70 were examined on their merits.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 12, 14 and 65 and 67 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The factors to be considered in determining whether undue experimentation is required are summarized In re Wands 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988). The court in Wands states: "Enablement is not precluded by the necessity for some experimentation such as routine screening. However, experimentation needed to practice the invention must not be undue experimentation. The key word is 'undue,' not 'experimentation.' " (Wands, 8 USPQ2d 1404). Clearly, enablement of a claimed invention cannot be predicated on the basis of quantity of experimentation required to make or use the invention. "Whether undue experimentation is needed is not a single, simple factual determination, but rather is a conclusion reached by weighing many factual considerations." (Wands, 8 USPQ2d 1404). The factors to be considered in determining whether undue experimentation is required include: (1) the quantity of experimentation necessary, (2) the amount or direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims. While all of these factors are considered, a sufficient amount for a *prima facie* case are discussed below.

It is clear that the pawpaw composition is an extract of the pawpaw fruit, which seems to closely resemble the juice of the pawpaw fruit. The juice is considered an 'extract' of the pawpaw fruit. It has not been demonstrated, in the Original disclosure, where an extract or fruit of pawpaw alone alleviated any wound as required by claims 12-14.

As an overview, Example 1 (A) is the pawpaw composition (p. 14, Specification).

The only examples in the specification which use the product of Example (1) alone are Example 18 (topical use for pain), Example 19(a) (topically for dry skin as a moisturizer), Example 19(b) (topical pain treatment) and Example 21 (topical, moisturizing).

The state of the art is unpredictable with regard to plant extracts was keenly provided in the previous Office action. The unpredictability of agents for treating wounds is equally unpredictable. Typically, to demonstrate the efficacy of a new wound healing agent; the agent should be capable of healing a wound more rapidly than the natural wound-healing process carried out in epithelial tissues. For example, such an agent would have the capability of augmenting the naturally-occurring wound healing process by mechanisms such as increasing epithelial cell growth or wound adhesion or collagen production. The Specification does not provide any evidence in the form of

examples; nor does the Specification teach that the pawpaw products of the claims provide for any mechanism which would aid in wound healing.

The scope of the required enablement varies inversely with the degree of predictability involved, but even in unpredictable arts, a disclosure of every operable species is not required. A single embodiment may provide broad enablement in cases involving predictable factors, such as mechanical or electrical elements. *In re Vickers*, 141 F.2d 522, 526-27, 61 USPQ 122, 127 (CCPA 1944); *In re Cook*, 439 F.2d 730, 734, 169 USPQ 298, 301 (CCPA 1971). However, in applications directed to inventions in arts where the results are unpredictable, the disclosure of a single species usually does not provide an adequate basis to support generic claims. *In re Soll*, 97 F.2d 623, 624, 38 USPQ 189, 191 (CCPA 1938). In cases involving unpredictable factors, such as most chemical reactions and physiological activity, more may be required. *In re Fisher*, 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970) (contrasting mechanical and electrical elements with chemical reactions and physiological activity).

Absent any indication in the Instant specification that the pawpaw compositions will work for treating a wound; coupled with the fact that the state of the art does not recognize pawpaw fruit, or components thereof for treatment of wounds, the claimed invention is not enabled. Considering this evidence, the skilled artisan, lacking information with regard to pawpaw having the ability to treat a wound would necessarily need to perform tedious trial and error protocols without expectation of success.

Considering that there is no evidence that a composition of pawpaw will treat a wound, it follows that prophylactically treating a patient susceptible to the occurrence of sores with a composition of pawpaw fruit is also not enabled. Claim 14, is directed toward a prophylactic treatment; meaning the ability of the agent to prevent a sore from occurring. The enablement standard for prevention is even higher than the enablement standard for treatment; and absent any evidence that pawpaw fruit will treat a wound, and absent any medicinal factors which the skilled artisan could predictably extrapolate to prevention of a sore, the claim is not enabled.

In re Fisher, 427 F.2d 833, 166 USPQ 18 (CCPA 1970), held that:

> "Inventor should be allowed to dominate future patentable inventions of others where those inventions were based in some way on his teachings, since such improvements while unobvious from his teachings, are still within his contribution, since improvement was made possible by his work; however, **he must not be permitted to achieve this dominance by claims which are insufficiently supported and, hence, not in compliance with first paragraph of 35 U.S.C. 112; that paragraph requires that scope of claims must bear a reasonable correlation to scope of enablement provided by specification to persons of ordinary skill in the art**; in cases involving predictable factors, such as mechanical or electrical elements, a single embodiment provides broad enablement in the sense that, once imagined, other embodiments can be made without difficulty and their performance characteristics predicted by resort to known scientific law; in cases involving unpredictable factors, such as most chemical reactions and physiological activity, scope of enablement varies inversely with degree of unpredictability of factors involved." (emphasis added)

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 6, 20, 63, 64 and 69-70 are rejected under 35 U.S.C. 102(b) as being anticipated by Schmidt, L. WAY DOWN YONDER IN THE PAWPAW PATCH; Intelligencer Journal, Lancaster, Pa. Oct. 02 (1996) pg. C1, pp. 1-3 from ProQuest Database.

Claims 6, 20, 63 and 64 are directed toward products produced by the processes according to either claim 1 or claim 2. Claims 1 and 2 recite processes, and hence, claims 6, 20, 63 and 64 are all in product-by-process format. Since the methods of claims 1 and 2 recite 'comprising' language, the method may be carried out with additional, unrecited, undisclosed method steps.

Schmidt (1996) writing for the Intelligencer Journal reported several recipes made with pawpaw fruit including pawpaw bread made with 1 cup mashed ripe pawpaw fruit (with skin and seeds removed), 1 teaspoon of baking soda and melted margarine (see p. 2).

This bread is deemed to anticipate the composition claims for the following reasons:

Schmidt taught addition of 1 teaspoon of baking soda (sodium bicarbonate) to one cup mashed fruit. One making the bread of Schmidt, adding the baking soda directly to the cup of mashed fruit would have added about 2% of a base having a pKa of less than 11 (i.e., baking soda, also known as sodium bicarbonate). Because the composition claims are product-by-process and because the process uses open language; the process may additionally include addition of auxiliary ingredients as well as the baking steps included by Schmidt to make a pawpaw bread. While Schmidt did not beat (required by claims 63 and 64 which are dependent upon claim 4) the batter prepared for the bread, Schmidt did mix the batter. It is determined that mixing or beating would not have changed the final product to such an extent to render the product novel over Schmidt absent evidence to the contrary. There is no specific time for beating and hence, claim 4 is broad enough to read on beating for a few seconds or less. It is further determined that heating the pawpaw fruit to the temperatures required by the claims prior to making the bread of Schmidt would not have changed the overall characteristics of the pawpaw bread.

Claim 69 recites a fruit and/or vegetable topical composition produced by the process of claim 2. Claim 70 is directed toward a fruit and/or vegetable derived topical composition produced by the process of claim 3. Claim 2 limits claim 1 to wherein the product is filtered to make a filtrate and a residue. Claim 3 limits claim 2 to wherein the mixture is frozen and thawed prior to filtering.

Claim 2 states nothing with regard to what type of filter is used and even though a filtrate and a residue is made, it does not state that they are separated, or how the residue distinguishes from the filtrate (e.g., if filtered through a very fine mesh, the product would lose some water) however, it is not determined that this product would be different from the product of Schmidt. Claim 3 states freezing and thawing which will not change the characteristics of the paw paw.

Hence, Schmidt anticipated the claimed invention.

The Examiner has considered the intended use for patentable weight. It is deemed that the intended use in the Instant claims does not materially change the composition in that the intended use does not materially change the composition. Applicant is asked to review *In re Hack*, 245 F.2d 246, 248, 114 USPQ 161, 163 (CCPA 1957). When the claim recites using an old composition or structure and the use is directed to a result or property of that composition or structure, then the claim is anticipated (MPEP 2100 pp. 2113). In the instant case, although the claims state 'topical composition' because the bread is not precluded from being used topically, the bread of Schmidt anticipates the claimed invention.

Claim Rejections - 35 USC § 102/103

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 6 and 7 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Schmidt, L. WAY DOWN YONDER IN THE PAWPAW PATCH; Intelligencer Journal, Lancaster, Pa. Oct. 02 (1996) pg. C1, pp. 1-3 from ProQuest Database.

The teachings of Schmidt were discussed above. Schmidt did not teach the pH of the pawpaw bread. However, since the pawpaw bread contained many ingredients with a high pH, the bread probably has a pH within or 'about' 7.5 to about 9.5 absent evidence to the contrary. Further, the adjustment of pH of a food product would have been well-within the purview of the ordinary artisan at the time the invention was made considering that pH is a result-effective variable. The ordinary artisan was well-aware of

the palatability changes which took place upon adjustment of pH in food compositions and adjusting the pH of a food composition to suit varying tastes is deemed obvious lacking any unexpected result.

"As a practical matter, the Patent Office is not equipped to manufacture products by the myriad of processes put before it and then obtain prior art products and make physical comparisons therewith." *In re Brown*, 459 F.2d 531, 535, 173 USPQ 685, 688 (CCPA 1972). The Patent and Trademark Office is not equipped to conduct experimentation in order to determine whether Applicants' composition differs and, if so, to what extent, from that of discussed references. Therefore, with the showing of the references, the burden of establishing non-obviousness by objective evidence is shifted to the Applicants.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-7, 12, 14, 20, 23-25, 27, 30, 32, 63-65 and 68 are rejected under 35 U.S.C. 103(a) as being unpatentable over Burchard (1999) in view of Purdue University and Blackstone, R. A GIFT TO AVOID THE YULE BUDGET JAM; The Province, Vancouver, B.C. Nov. 17, 1993, pg. B 8, pp. 1-2 of ProQuest, (1993) and Schmidt, L. WAY DOWN YONDER IN THE PAWPAW PATCH; Intelligencer and Burckhardt, A. QUICK PICKLES AND JAMS; Minneapolis Star and Tribune, Minneapolis, Minn; July 16, 1986; p. 03 T, pp. 1-6 of ProQuest Database.

Burchard, H. reporting for The Washington Post (1999) taught that pawpaw, known botanically as *Asimina triloba*, was an endogenous, fruit-bearing plant of the Eastern United states as well as Canada, often harvested for it's edible fruit as well as the fruit's medicinal and insecticidal properties (see pp. 1-2). Burchard indicated pawpaw fruit to be used in various food items such as milkshakes, baked goods, pina coladas, pie, ice cream, chutney and brandy. Burchard specifically disclosed a recipe for pawpaw fruit jam which included combining pawpaw pulp, water, applesauce, apple juice, lime juice, sugar and pectin, stirring, bringing to a boil (100 °C), 'stirring constantly' and pouring into jelly jars (see entire reference, especially page 4).

Burchard did not specifically teach wherein pawpaw fruit jam was mixed with about 1 to 40% or 3-14% of a base having a pKa of less than 11 (Applicant's elected species is sodium bicarbonate), filtering, beating, freezing and thawing prior to filtering, wherein the fruit pulp was heated to about 40 °C to 70° or from about 50° C to 60 °C.

Purdue University Online (PUO)(archived to 2001) teaches that pawpaw; known by its botanical name of *Asimina triloba*, was well known for its edible fruit; used as a food source containing larger amounts of vitamins, minerals, amino acids and food energy than apple, peach or grape (pp. 1-2). PUO reported that the pawpaw fruit are useful for making food products such as blended fruit drinks, baby food, ice cream, puree and frozen food products. PUO additionally noted the cosmetic potential of the pawpaw fruit (p. 2).

Fruit jellies are often made with the addition of bicarbonates in order to strengthen the jelly compositions and to provide longer shelf-life according to Wallerstein (US 1,997616). Wallerstein teaches the addition of 1 part of magnesium carbonate (magnesium bicarbonate- $MgCO_3$) to 30 to 50 parts of pectin (see p. 1, col. 2). (pectin compositions are added to fruit/fruit juices to produce jellies and jams).

Blackstone, reporting for The Province. Vancouver, B.C.: Nov 17, 1993. pg. B.8, pp. 1-2 of ProQuest indicated that the fruit used in jams could be heated prior to addition of pectin and sugar; and thereby the fruit was heated prior to boiling (see p. 1).

Schmidt, L. reporting for the Intelligencer Journal of Lancaster, PA, reported several recopies using pawpaw fruit including a pawpaw bread and zabaglione and ice cream; wherein the seeds and peel were removed prior to use (see pp. 2-3).

Although the prior art does not specifically teach heating the fruit to the specific temperatures as required by the claims ordinary artisan would have had a reasonable expectation that heating pawpaw to these temperatures would have enabled any additionally added sugar to dissolve into a pawpaw jelly/jam composition. Further, it is clear from the prior art that jams were prepared by first heating fruit at a temperature below boiling prior to boiling to dissolve the sugar and pectin into the fruit. Hence, the choice of temperature ranges as claimed are deemed within the purview of the ordinary artisan at the time the invention was made in order to heat the fruit to homogenize the fruit mixture and could have been achieved through routine experimentation. It is clear that the prior art taught heating the fruit composition prior to making jams/jellies.

The ordinary artisan would have had a reasonable expectation of success in producing a pawpaw jam with the addition of a bicarbonate as taught by Wallerstein in order to increase the stability/shelf life of a pawpaw jelly or jam.

It has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 220 F2d 454,456,105 USPQ 233; 235 (CCPA 1955). see MPEP § 2144.05 part II A. It would have been obvious to one of ordinary skill in the art at the time Applicants' invention was made to determine all operable and optimal concentrations of bicarbonate, because this component was an art-recognized result-effective variable which would have been routinely determined and optimized in the food art. Further, if there are any differences between Applicant's claimed method and that suggested by the combined teaching of the prior art, the differences would be appear minor in nature.

Hence, the steps for producing the pawpaw composition as claimed is deemed obvious considering that pawpaw fruits are well-known in the art to be an edible fruit which is prepared into food compositions such as jams. The alterations of temperature and amounts of bicarbonate in the claim are deemed within the level of the ordinary artisan at the time the invention was made in order to vary these parameters under normal working conditions to prepare pawpaw jams and jellies: "[a] person of ordinary skill is also a person of ordinary creativity, not an automaton *KSR* 127S. Ct. at 1742.

Hence, absent any unexpected results, these variations are not deemed patentable over the prior art teachings.

With regard to claim 5 which states "wherein the mixture obtained in step (c) has a pH in the range of about 7.5 to about 9.5," Applicant is directed to MPEP § 2111.04:

> The determination of whether each of these clauses is a limitation in a claim depends on the specific facts of the case. In Hoffer v. Microsoft Corp., 405 F.3d 1326, 1329, 74 USPQ2d 1481, 1483 (Fed. Cir. 2005), the court held that when a "whereby' clause states a condition that is material to patentability, it cannot be ignored in order to change the substance of the invention." Id. However, the court noted (quoting Minton v. Nat 'l Ass 'n of Securities Dealers, Inc., 336 F.3d 1373, 1381, 67 USPQ2d 1614, 1620 (Fed. Cir. 2003)) that a ***"whereby clause in a method claim is not given weight when it simply expresses the intended result of a process step positively recited."*** Id.< (emphasis added).

Hence, it follows from *Minton v. Nat 'l Ass 'n of Securities Dealers, Inc.*, 336 F.3d 1373, 1381, 67 USPQ2d 1614, 1620 (Fed. Cir. 2003) that claim 5 simply 'expresses the intended result of a process step' and is thus not given patentable weight.

KSR forecloses the argument that a specific teaching, suggestion, or motivation is required to support a finding of obviousness. See the recent Board decision *Ex parte Smith*, --USPQ2d--, slip op. at 20 (Bd. Pat. App.& Interf. June 25, 2007) (citing KSR, 82 USPQ2d at 1396)

Clearly, Schmidt taught the removal of the skin and seeds. While Schmidt did not explicitly teach filtering or straining the seeds; the ordinary artisan would have been motivated to strain the fruit to remove the seeds for example prior to making a jam. Clearly, some prefer to use the pawpaw fruit without the seeds for making pawpaw food products. Hence, straining the fruits would have been a viable option for those wishing to remove the seeds of the fruit prior to making a jam or jelly from pawpaw fruit.

One of ordinary skill in the art would have been motivated to freeze pawpaw fruit after harvesting in order to save it for a time prior to making jam; whereby the fruit would then be processed into a jam which could include the steps as recited by the claims. Clearly, freezing fruits and fruit juices was routine in the art of jam-making as indicated by Burckhardt.

Although the prior art did not expressly teach 'beating' the pawpaw fruit mixture to create a pawpaw jam; it is clear that Burchard (1999) stirred their mixture. The difference between beating and stirring is decidedly insignificant and hence, the ordinary artisan would have recognized that beating could be substituted for mixing in the recipe of Burchard.

The Supreme court has acknowledged that:

> When a work is available in one field of endeavor, design incentives and other market forces can prompt variations of it, either in the same field or a different one. **If a person of ordinary skill can implement a predictable varition..103 likely bars its patentability**...if a technique has been used to improve one device, and a person of ordinary skill in the art would recognize that it would improve similar devices in the same way, using the technique is obvious unless its actual application is beyond that person's skill. A court must ask whether the improvement is more than the predictable use of prior-art elements according to their established functions...
>
> ...**the combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results** (see *KSR International Co. v. Teleflex Inc.*, 82 USPQ2d 1385 U.S. 2007) emphasis added.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Response to Arguments

35 USC 102(b):

Applicants essentially argue that the Examiner has not made a *prima facie* case of anticipation y asserting that the prior art does not specifically teach that the pulp is heated in the range specified by part (b) of claim 1: "The Official Action appears to discount this recited claim feature, and merely provides the following unsupported conclusory statements:

> It is determined that mixing or beating would not have changed the final product to such an extent to render the product novel over Schmidt absent evidence to the contrary...It is further determined that heating the pawpaw fruit....would not have change the overall characteristics of the bread." (p. 7, Remarks).

"[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985).

Applicants have not provided any information/evidence that would demonstrate that the product of claims 6, 20, 63, 64 and 69-70 are in any way different from the

product of Schmidt. First, claim 6 states 'obtainable from' the process of claim 1 and therefore, the product does not require the steps of the claim. Notwithstanding this fact of the claim, part (b) of claim 1 states 'heating said fruit and/or vegetable pulp up to a temperature in the range of about' thus indicating that the temperature can be any temperature in the range of about 40 °C to 70°C or below. The claim does not state a particular length of time that the product is heated and therefore, the product may be heated for a fraction of a second. The Examiner cannot determine that heating to 40 °C to 70°C or below would change the product obtained from Schmidt (e.g., the bread prior to baking).

Applicants assert that the clinical data (Exhibits 1 and 2) provide evidence that "a composition made by the process of claim 1 indeed has unexpected ulcer and wound healing characteristics...process of claim 1 and its recited features are critical to attaining these unexpected results." (p. 7, Remarks).

It is first pointed out that any Evidence submitted on the record to support an enablement rejection which Applicants would like analyzed by the Examiner should be in the form of a signed Affidavit/Declaration. A discussion of the evidence presented in the Exhibits will follow.

In order for the product claims to overcome the prior art, the claims must be patentably distinct from the prior art. In the Instant case, the claims are anticipated by

the prior art because Applicant's product-by-process claims are so broad as to cover products which were not disclosed in the Instant application. The Examiner has considered the claims as a whole as to their entire breadth. In analyzing the claims for patentability, the Examiner gives the claims their broadest, reasonable interpretation. The Examiner does not read limitations from the Specification into the claims (unless duly warranted). It is noted that the claims are much broader in scope than the preferred embodiments in the specification and include embodiments which are not disclosed and/or claimed.

As discussed in previous Office actions, the process for making which uses comprising language may include additional undisclosed, unclaimed steps. In addition, claim 6 states 'obtainable by' which indicates that the product may actually be made by a different process. Additionally, if the composition of the claims is determined to be broad enough that a product already disclosed in the art anticipates such claims (e.g., Schmidt) unexpected results are not sufficient to overcome the rejection under 35 USC 102(b) because this rejection is a statutory bar. It is suggested that the claims be amended to recite more narrow language to distinguish the claimed product from products of the prior art.

Additionally, there is no evidence of an unexpected result and again, unexpected results are not sufficient to overcome statutory bar rejections.

102/103:

Applicants essentially argue that the Examiner has not made a *prima facie* case and cites "a court must ask whether the improvement is more than the predictable use of prior art elements….it [may] be necessary for a court to look to interrelated teachings…effects of demands known to the design community…it can be important to identify a reason that would have prompted a person of ordinary skill …to combine the elements in the way the claimed new invention does…claimed discoveries almost of necessity will be combinations of what, in some sense, is already known…Second, the proposed modification…must have had a reasonable expectation of success…Amgen Inc. v. Chugai Pharm…the prior art references must teach or suggest all the limitations of the claims…In re Wilson" (p. 9, Remarks).

However, the 102/103 rejection is a hybrid rejection. This rejection was placed on record because it appears that the prior art product is the same product as claimed. The MPEP states:

II. A REJECTION UNDER 35 U.S.C. 102/103 CAN BE MADE WHEN THE PRIOR ART PRODUCT SEEMS TO BE IDENTICAL EXCEPT THAT THE PRIOR ART IS SILENT AS TO AN INHERENT CHARACTERISTIC

Where applicant claims a composition in terms of a function, property or characteristic

and the composition of the prior art is the same as that of the claim but the function is not explicitly disclosed by the reference, the examiner may make a rejection under both 35 U.S.C. 102 and 103, expressed as a 102/103 rejection. "There is nothing inconsistent in concurrent rejections for obviousness under 35 U.S.C. 103 and for anticipation under 35 U.S.C. 102." In re Best, 562 F.2d 1252, 1255 n.4, 195 USPQ 430, 433 n.4 (CCPA 1977). This same rationale should also apply to product, apparatus, and process claims claimed in terms of function, property or characteristic. Therefore, a 35 U.S.C. 102/103 rejection is appropriate for these types of claims as well as for composition claims.

V. ONCE A REFERENCE TEACHING PRODUCT APPEARING TO BE SUBSTANTIALLY IDENTICAL IS MADE THE BASIS OF A REJECTION, AND THE EXAMINER PRESENTS EVIDENCE OR REASONING TENDING TO SHOW INHERENCY, THE BURDEN SHIFTS TO THE APPLICANT TO SHOW AN UNOBVIOUS DIFFERENCE

"[T]he PTO can require an applicant to prove that the prior art products do not necessarily or inherently possess the characteristics of his [or her] claimed product. Whether the rejection is based on inherency' under 35 U.S.C. 102, on *prima facie* obviousness' under 35 U.S.C. 103, jointly or alternatively, the burden of proof is the same...[footnote omitted]." The burden of proof is similar to that required with respect to product-by-process claims. *In re Fitzgerald*, 619 F.2d 67, 70, 205 USPQ 594, 596 (CCPA 1980) (quoting *In re Best*, 562 F.2d 1252, 1255, 195 USPQ 430, 433-34

(CCPA 1977)).

Applicant argues that "[s]ince Schmidt does not teach or suggest the process recite[d] in claim 1…Schmidt also does not teach or suggest a fruit and/or vegetable derived composition obtainable from the process of claim 1." (pp. 9-10, Remarks). However, again, the claims are in product-by-process format and are determined to read on the product of Schmidt for the reasons addressed supra.

Applicants argue that the pH of the bread of Schmidt would not have a pH of 'about 7.5 to about 9.5' and indicates that Exhibit #2 is provided 'showing the US FDA listing of 'Approximate pH of Foods and Food Products.' However, this exhibit does not indicate that the bread of Schmidt will not have a pH of 'about 7.5 to about 9.5.' The foods listed on this page are more than likely commercial products; while the bread of Schmidt does not appear to be commercially produced. Nevertheless, the exhibit does not provide information concerning the bread of Schmidt.

Applicant argues that Schmidt does not disclose that many ingredients have a high pH and lists several ingredients having a pH below 7. This list is accepted. However, Applicant does not list the pH of pawpaw fruit, but instead states 'Nearly all fruits on the [FDA] list, and most vegetables, have a pH less than 7." PawPaw fruit is not on this list. Schmidt uses one cup pawpaw fruit in the mixture which will contribute to the overall pH of the bread. Galli et al. (2008) indicate that pawpaw fruit (*A. triloba*)

has a pH of 7.4 on the day of harvest and a pH of 7.2 upon until week 8 after harvest under cold conditions (see Table 1). The pawpaw fruit, when fresh has a pH of about 7.2. Schmidt touts the use of 'fresh paw paw' and hence, such fresh paw paw would more than likely have a pH of around 7.2 and contribute to raising the pH of the bread composition. Again, a pH of 7 or 7.2 is, in the opinion of the Examiner, within the realm of 'about 7.5' absent evidence to the contrary and absent any requisite degree of knowledge concerning what 'about a pH of 7.5' would include.

Thus, Applicant's arguments were carefully considered, but not found persuasive to overcome the rejection.

Applicant further argues that the ordinary artisan would not have a reasonable expectation of success in creating the claimed composition (pp. 11-12). Applicant asserts that compositions are typically adjusted to have lower pH values 'or to pH values that are less acidic but still significantly less than pH 7.5.' "...lowering the acidity of food is preferred in order to maintain food safety by inhibiting the growth of microorganisms." However, the ordinary person in the art is not only the commercial bread maker; on the contrary, the ordinary person in this art are chefs, general persons in the food industry or ordinary people who experiment with food recipes. Further, again, the claim states 'about 7.5' which is not 7.5 but is 'about 7.5' which may read on 7.0 or 7.2 for example.

Applicant argues that there is an unexpected result as assertedly provided by Exhibits 1 and 2 (pp. 12-13, Remarks). However, the Examiner cannot determine any evidence of an unexpected result, and if it were determined that the composition shown in Exhibits 1 and 2 provided for such a result, the composition of Exhibits 1 and 2 are much narrower in scope than the breadth of the currently claimed invention allows. Thus, if an unexpected result was found to be demonstrated, the scope of the claims would not be commensurate with such a result. The composition shown to heal ulcers is but one embodiment found in the breadth of the claims- Applicant has not established that the product of the claims is novel and unobvious over the product of Schmidt and although the product which is shown in the Exhibits displays a different result, does not establish an unexpected result, especially considering that examination of the breadth of the claims indicates that the claimed composition is anticipated or obvious over Schmidt. Additionally, the evidence supplied by Applicant is apparently directed toward the use of papaya , whereby the Instant claims are being examined with regard to the species of paw paw which is *Asimina triloba*. Therefore, results pertaining to the use of papaya are not particularly relevant to *Asimina triloba*.

35 USC 103(a)

Applicant argues that the references do not teach or suggest all of the recited limitations of the claims (p. 16, Remarks). However, KSR forecloses the argument that a specific teaching, suggestion, or motivation is required to support a finding of obviousness. See the recent Board decision *Ex parte Smith*, --USPQ2d--, slip op. at 20 (Bd. Pat. App.& Interf. June 25, 2007) (citing KSR, 82 USPQ2d at 1396). Specifically, Applicants argue that the combination of references does not teach or suggest mixing 'a base having a pKa of less than 11 with the heated fruit/and/or vegetable pulp of step (b) whilst said pulp has a temperature in the range specified in step (b)...combination does not teach or suggest mixing the base with the heated pulp while the pulp is at 'a temperature in the range of about 40 ° C to 70 °C.' (p. 16, Remarks).

However, first, the Examiner pointed out that heating to the particular temperature range would have been within the purview of the ordinary artisan (pp. 14-15, FAOM 10/16/2010). Further, the Examiner reasoned that one of ordinary skill in the art would have had a reasonable expectation of heating the combination of Burchard at temperatures below boiling because jams were generally known to be heated prior to the addition of pectin and sugar (and prior to boiling) as disclosed by Blackstone.

Applicant argues that Wallerstein obtained a 'substantial decrease in jelly strength' and 'not fully satisfactory' uniformity when magnesium carbonate was replaced with sodium bicarbonate....Wallerstein's results suggest that it was the magnesium ion which is [the, sic] critical to achieving the desired properties and not necessarily the carbonate alone.' (p. 17, Remarks). However, this does not detract from the teachings

of Wallerstein which show that the amounts of bicarbonate were varied in jelly compositions.

Applicant argues that '..there is no teaching or suggestion to heat the fruit composition prior to adding the base.' (p. 17). However, this is considered an obvious modification of the prior art. It is clear that jelly preparations are often heated to dissolve the sugar prior to boiling and the addition of the base to the already-heated fruit composition would have been an obvious variation, within the skill level of the ordinary artisan.

Applicant again asserts '...to obtain the unexpectedly useful topical composition of the present claims.' (p. 17). However, Applicant has not provided any evidence with regard to an unexpected result over the examined species of paw paw, that being *A. triloba*.

Applicant traverses the Examiner's finding that the limitation of claim 5 which states 'wherein the mixture obtained in step (c) has a pH in the range of about 7.5 to about 9.5' is a non-limitation. specifically, Applicant argues that 'Claim scope is not limited by claim language that suggests or makes optional but does not require steps to be performed, or by claim language that does not limit a claim to a particular structure' (MPEP § 211.04). Applicant asserts that said limitation structurally limits the claim to a composition having the specified pH range.' (p. 18, Remarks). However, Applicant's

remarks state that the limitation limits the claim to a composition...The claims are not composition claims, rather, they are method claims and method claims are examined by a different means than composition claims. One difference in examination is provided by MPEP 2111.04 : "a whereby clause in a method claim is not given weight when it simply expresses the result of a process step positively recited." This is because it is the process steps which are being examined, and if the process steps which occur in the prior art are the same, or similar to the steps performed in the claims, the claims are said to be anticipated or obvious even if they do not carry-out the intended function of the claims. Thus, Applicant's argument that 'a composition having a specified pH range very clearly has a very specific limit on structure' is explicitly refering to a composition claim, and not a method claim and thus is not particularly pertinent to the argument. 'Compositions not having the hydrogen ion concentration indicated by the recited pH range are not encompassed by the claim' is respectfully not accepted: again, claim 5 is a method claim, and not a composition claim.

Applicant argues that 'the Official Action might be placing too much emphasis on examining the claimed subject matter in view of the food arts....[t]he claimed subject matter is not a food composition or a food process..." However, this statement is unsubstantiated. The composition of the claims is a food product because there is nothing excluding the composition as being a food or being consumed as a food product. Additionally, paw paw fruit was known to be processed in to jams and jellies. It is the opinion of the examiner that with regard to the composition claims there is no or

little difference between the composition of the claims and the compositions suggested by the prior art. Applicant argues that '[t]he claims clearly recite that the obtained composition is a topical composition.' However, this is merely an intended use, whereby the products of the prior art, if used in an art rejection cannot be precluded for topical use. Merely because Applicant uses the claimed invention as a pharmaceutical, does not preclude the placing of prior art documents which anticipate or make obvious the claimed invention. ' A pharmaceutical composition comprising lycopene' may in fact be a pharmaceutical; but it is not precluded from being anticipated by a tomato which is a food product. The use of food products and/or herbal products in the pharmaceutical fields is ubiquitous and thus the overlap of art between food products and herbals is extensive. The Examiner in the Instant case must properly traverse arts upon searching the invention in order to determine patentability of the claims.

Applicant argues that one of ordinary skill in the art would not be motivated to arrive at the claimed invention; and implies that the references are unrelated (pp. 21-22, Remarks). However, it is the opinion of the Examiner that one wishing to make a paw paw jelly or fruit would obtain the above references in order to determine how to prepare such a fruit jelly. The composition of the claims is deemed obvious for the reasons given above and the references are not considered disparate; on the contrary, all of the references provide information regarding paw paw and creating fruit jams .

112 First Rejection

Applicant's arguments concerning this rejection center around the basis that the Exhibits (1 and 2) provide evidence to support the enablement of the claimed invention. It is pointed out that the Declaration by Neal Peterson ('Declarant') was fully considered, Mr. Peterson's *Curriculum Vitae* being duly noted. It is accepted, based upon the statements by Mr. Peterson, that paw paw may also be considered as papaya. However, the specification does not list alternatives for the genus of paw paw and therefore, the phrase 'paw paw' given it's broadest interpretation may be one of *A. triloba* (Hoosier banana) or papaya. The evidence given in the Exhibits is directed toward papaya; the Instant claims are being examined for *A. triloba* as they have been since the beginning of prosecution. Hence, the evidence submitted is not relevant to the species of paw paw being examined; and such arguments pertaining to the alleged evidence is therefore not found to be convincing to obviate the outstanding rejection. Additionally, such evidence should be presented as an Affidavit or Declaration.

Conclusion

No claims are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia Leith whose telephone number is (571) 272-0968. The examiner can normally be reached on Monday - Friday 8:30am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on (571) 272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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Primary Examiner
Art Unit 1655

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